



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 15 2004

Paul Anand, Ph.D.
Director
BioDiagnostic International
615 North Berry St. # E
Brea, CA 92821

Re: k031296
Trade/Device Name: LIQUI-HEME Glycohemoglobin A1c Assay
LIQUI-HEME Hemoglobin A1c Control Set
LIQUI-HEME Hemoglobin A1c Calibrators
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, KRZ, JJX
Dated: October 1, 2004
Received: October 4, 2004

Dear Dr. Anand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

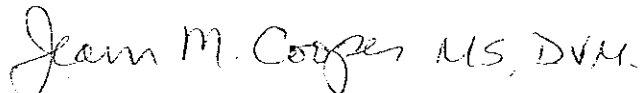
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Jean M. Cooper MS, D.V.M.".

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k031296**

Device Name: LIQUI-HEME Glycohemoglobin A1c Assay

Indications For Use:

The BioDiagnostic Intl LIQUI-HEME Glycohemoglobin A1c Test kit is an *In Vitro Diagnostic* reagent for the quantitative determination of Glycohemoglobin A1c (HbA1c) in the human whole blood. The method is an immunological assay. Both the concentration of HbA1c and the concentration of the total hemoglobin are measured. The reported HbA1c result is calculated as a percentage of the total hemoglobin concentration.

Measurements of percentage HbA1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

This application sheet has been developed for the Hitachi instrument of clinical chemistry analyzer and must be used by suitably qualified personnel under appropriate clinical laboratory conditions.

Further, this test kit also includes a set of six calibrators and bilevel(Human) Low and High controls, which are optional.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

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Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k031296